TRANSMITTAL AND NOTICE OF APPROVAL OF	1. TRANSMITTAL NUMBER:	2. STATE	
STATE PLAN MATERIAL	2004-030	Florida	
•	2 PROCE AM IDENTIFICATION: TO	TI E VIV OF THE	
FOR: HEALTH CARE FINANCING ADMINISTRATION	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)		
TO: REGIONAL ADMINISTRATOR	4. PROPOSED EFFECTIVE DATE		
HEALTH CARE FINANCING ADMINISTRATION	July 1, 2004		
DEPARTMENT OF HEALTH AND HUMAN SERVICES	July 1, 2004		
5. TYPE OF PLAN MATERIAL (Check One):			
☐ NEW STATE PLAN ☐ AMENDMENT TO BE O	CONSIDERED AS NEW PLAN		
COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AME		n amendment)	
6. FEDERAL STATUTE/REGULATION CITATION:	7. FEDERAL BUDGET IMPACT:		
42 CFR 440.120		45	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	b. FFY 2005 \$3 9. PAGE NUMBER OF THE SUPERS	598	
Attachment 3.1-A, page 46	OR ATTACHMENT (If Applicable):		
Attachment 3.1-B, page 45	Attachment 3.1-A, page 46		
Timemient 3.1 2, page 13	Attachment 3.1-B, page 45		
	71.5		
10. SUBJECT OF AMENDMENT:			
Change in Access Limitations to Influenza Vaccine			
11. GOVERNOR'S REVIEW (Check One):			
☐ GOVERNOR'S OFFICE REPORTED NO COMMENT	☑ OTHER, AS SPECIFIED:		
COMMENTS OF GOVERNOR'S OFFICE ENCLOSED	Will forward when received.		
☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL			
12. SIGNATIURE OF STATE AGENCY OFFICIAL:	16. RETURN TO: Mr. Thomas W. Arnold		
Chw Cul	Deputy Secretary for Medicaid		
13. TYPED NAME:	Agency for Health Care Administration		
Mr. Thomas W. Arnold	2727 Mahan Drive, Mail Stop #8		
14. TITLE:	Tallahassee, FL 32308		
Deputy Secretary for Medicaid	4		
15. DATE SUBMITTED	Attention: Kay Newman		
FOR REGIONAL OF	RECEUSEONLY		
17. DATE RECEIVED:	18. DATE APPROVED:		
September 21, 2004	October 1	8, 2004	
PLAN APPROVED - ON			
19. EFFECTIVE DATE OF APPROVED MATERIAL:	20. SIGNATURE OF REGIONAL OF	FICIAL:	
July 1, 2004	Kinard L Munay		
21. TYPED NAME:	22. TITLE: Associate Region		
Renard L. Murray, D.M.	Division of Medicaid & Ch	ildren's Health	
23. REMARKS:			
	<i>.</i> 		

Covered outpatient drugs are those produced by any manufacturer, which has entered into and complies with an agreement under Section 1927(a) of the Act, which are prescribed for a medically accepted indication. All Medicaid recipients 21 years of age and older will be limited to four brand-name drugs per month. There are no instances in which recipients under the age of 21 have system limitations placed on the number of prescriptions, brand or multi-source, they may receive. Generic drugs, insulin and diabetic supplies, contraceptives, mental health drugs, and anti-retroviral drugs are exempt from these limits. Based on the treatment needs of the Medicaid recipients, the agency may authorize exceptions to the brand-name-drug restriction. These exceptions will be based on prior consultation by the prescriber with the agency or agency contractor. Approved smoking cessation and nicotine replacement products are covered services. As provided by Section 1927(d)(2) of the Act, certain outpatient drugs may be excluded from coverage. Those excluded are DESI drugs; experimental drugs; anorectics (unless prescribed for an indication other than obesity); non-legend drugs (except insulin, aspirin, aluminum and calcium products used as phosphate binders, sodium chloride for specific medical indications, and OTC vaginal antifungals that have previously been legend drugs, when prescribed); and any drugs for which the manufacturer has not entered into rebate agreements with the Department of Health and Human Services, the Veteran's Administration and the Public Health Service. Cough and cold preparations are not covered services for recipients 21 years of age and older. Vitamin and mineral products are covered only under the following circumstances: prenatal vitamins; folic acid as a single entity; fluorinated pediatric vitamins; one vitamin or vitamin/mineral prescription monthly for a dialysis patient; and prescribed ferrous sulfate, gluconate, or fumarate for non-institutionalized patients. (Ferrous sulfate, gluconate, or fumarate is equally available as floor stock to institutionalized patients.) Non-Child Health Check-Up 221 recipients 21 years of age and older immunizations are limited only to influenza and pneumococcal vaccines. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages.

<u>Drug Rebate Agreement:</u> The state is in compliance with Section 1927 of the Act. Based on the requirements for Section 1927 of the Act, the state has the following policies for drug rebate agreements:

- The drug file permits coverage of participating manufacturers' drugs.
- Compliance with the reporting requirements for state utilization information and restrictions to coverage.
- A rebate agreement, Version 07/02/03, between the state and a drug manufacturer that is separate from the drug rebate agreements of Section 1927 is authorized by the Centers for Medicare and Medicaid Services. The agreement to be used between the State of Florida and drug manufacturers for supplemental rebates for drugs provided to the Medicaid population has been reviewed and authorized by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any cash state supplemental rebates collected.
- Manufacturers are allowed to audit utilization data.
- The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- Prior authorization programs provide for a 24-hour turn-around on prior authorization from receipt of request, and at least a 72-hour supply in emergency situations.

Amendment 2004-030 Effective 07/01/2004 Supersedes 2003-01 Approved 10/18/2004 Revised submission Covered outpatient drugs are those produced by any manufacturer, which has entered into and complies with an agreement under Section 1927(a) of the Act, which are prescribed for a medically accepted indication. All Medicaid recipients 21 years of age and older will be limited to four brand-name drugs per month. There are no instances in which recipients under the age of 21 have system limitations placed on the number of prescriptions, brand or multi-source, they may receive. Generic drugs, insulin and diabetic supplies, contraceptives, mental health drugs, and anti-retroviral drugs are exempt from these limits. Based on the treatment needs of the Medicaid recipients, the agency may authorize exceptions to the brand-name-drug restriction. These exceptions will be based on prior consultation by the prescriber with the agency or agency contractor. Approved smoking cessation and nicotine replacement products are covered services. As provided by Section 1927(d)(2) of the Act, certain outpatient drugs may be excluded from coverage. Those excluded are DESI drugs; experimental drugs; anorectics (unless prescribed for an indication other than obesity); non-legend drugs (except insulin, aspirin, aluminum and calcium products used as phosphate binders, sodium chloride for specific medical indications, and OTC vaginal antifungals that have previously been legend drugs, when prescribed); and any drugs for which the manufacturer has not entered into rebate agreements with the Department of Health and Human Services, the Veteran's Administration and the Public Health Service. Cough and cold preparations are not covered services for recipients 21 years of age and older. Vitamin and mineral products are covered only under the following circumstances: prenatal vitamins; folic acid as a single entity; fluorinated pediatric vitamins; one vitamin or vitamin/mineral prescription monthly for a dialysis patient; and prescribed ferrous sulfate, gluconate, or fumarate for non-institutionalized patients. (Ferrous sulfate, gluconate, or fumarate is equally available as floor stock to institutionalized patients.) Non-Child Health Check-Up 221 recipients 21 years of age and older immunizations are limited only to influenza and pneumococcal vaccines. Drugs must be prescribed and dispensed in accordance with medically accepted indications for uses and dosages.

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